K060224

MAR 6 2006

510(k) Summary

Submitted By:

Thalia Brine
Regulatory Affairs Specialist
Cook Incorporated
750 Daniels Way, P.O. Box 489
Bloomington, IN 47402
812.339.2235

27 January 2006

Device:

Trade Name:	Mira-Flex™ 18 Microcatheter
Proposed Classification:	Catheter, Continuous Flush KRA

Predicate Devices:

The Mira-Flex™ 18 microcatheter is similar in terms of intended use, materials, and technological characteristics to the predicate device reviewed as a device for the delivery of thrombolytic therapy or embolic devices in tortuous or superselective anatomy.

Device Description:

The Mira-Flex™ 18 microcatheter is an infusion catheter with a hydrophilic coating, designed for use in small vessel or superselective anatomy for diagnostic and interventional procedures, including neuro, peripheral, or coronary use. This device will be available with a 2.5 French shaft, and is compatible with 0.018" embolization coils and appropriately-sized embolization particles. The device will be supplied sterile, and is intended for one-time use. The Mira-Flex™ 18 will be available in 100, 110, 135, and 150 cm lengths.

Substantial Equivalence:

This device will be manufactured according to specified process controls and a Quality Assurance Program. The device will undergo packaging similar to the devices currently marketed and distributed by Cook Incorporated. This device will undergo sterilization similar to devices currently marketed and distributed as well. Being similar with respect to indications for use, materials, and physical construction to the predicate device, this device meets the requirements for section 510(k) substantial equivalence.

Test Data:

The Mira-Flex™ 18 microcatheter was subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests were:

1. Tensile tests
2. Burst and pressure tests
3. Biocompatibility tests
4. Leakage tests
5. Acute animal study

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its use as an infusion catheter in tortuous or superselective anatomy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 6 2006

Cook Incorporated
c/o Ms. Thalia Brine
Regulatory Affairs Specialist
P.O. Box 489
Bloomington, IN 47402-0489

Re: K060224
Mira-Flex™ 18 Microcatheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous flush catheter
Regulatory Class: II
Product Code: KRA
Dated: February 16, 2006
Received: February 17, 2006

Dear Ms. Brine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vo Ames

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K060224

Device Name: Mira-Flex™ 18 microcatheter

Indications for Use:

The Mira-Flex™ 18 microcatheter is designed for use in small vessel or superselective anatomy for diagnostic and interventional procedures including neuro, peripheral, or coronary use. Supplied sterile in peel-open packages. Intended for one-time use.

Prescription Use X OR Over-the-Counter Use

(Per 21 CFR 801 Subpart D) (Per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Devices

510(k) Number K060224